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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,144	12/29/2003	Daniel M. Gorman	DX01170K1	4801

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,144

Applicant(s)

GORMAN, DANIEL M.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/07 & 8/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 01 November 2007 is acknowledged and entered. Following the amendment, claims 21-32 are canceled, and the new claims 33-35 are added.

Currently, claims 33-35 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 21-26 are moot as the applicant has canceled the claims.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 11/2/07 is acknowledged, and has been considered. A signed copy is attached hereto.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite for the recitation "the *mature sequence* in SEQ ID NO:24 and the *extracellular domain* of the human IL-17RE" of SEQ ID NO:12 as neither the claim nor the specification defines the terms of "mature sequence" and the "extracellular domain". The metes and bounds of the claim, therefore, cannot be determined.

Claim 34 is indefinite because it is dependent from a canceled claim, claim 21.

The remaining claim is included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 33-35 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al., US6,569,645, for the same reasons addressed in the prior art rejection of claims 21-26 under 35 U.S.C. 102(a) as being anticipated by the same reference, set forth in the last Office Action mailed on 01 June 2007, at page 8.

The teachings of Chen were reviewed in the last Office Action, and are reiterated below: Chen discloses a newly identified protein termed IL-17C (PRO1122), which amino acid sequence of SEQ ID NO:4 is 100% identical to the present IL-17C of SEQ ID NO:24 (column 4, lines 48-49), and stimulates TNF- α production (column 132, lines 33-36). Additionally, Chen teaches antibodies to the protein, including polyclonal, monoclonal, humanized antibodies (column 84, lines 5-8). Further, Chen teaches that compounds, e.g., antibodies, which bind to stimulating PRO polypeptides and block the stimulating effect of the molecules produce a net inhibitory effect and can be used to suppress the T cell mediated immune response by inhibiting T cell proliferation/activation and/or lymphokine secretion, and blocking the stimulating effect of the polypeptides suppresses the immune response of the mammal (column 78, lines 34-40), and can be used to treat T cell mediated diseases, including, among others, psoriasis (column 92, lines 63-66; and column 93, line 31); and that psoriasis is a T lymphocyte-mediated inflammatory disease (column 96, lines 54-55). Thus, the reference teaches the use of antibodies (including humanized antibodies) to IL-17C for the treatment of diseases such as psoriasis, and therefore, anticipates the present claims.

Applicants argument filed on 01 November 2007 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 6-7 of the response, the applicant argues that it is well settled law that an anticipating reference must explicitly or inherently describe all of the elements and limitations of the claim, and must enable one of skill in the field of the invention to make and use the claimed invention, and that a claim limitation is inherent in the prior art only if the limitation is necessarily present in the prior art, not merely probably or possibly present; that Chen does not describe or enable antibodies with all the properties required by the present claims 33-36, as the reference does not describe any such antibodies that were actually made while it generically describes antibodies that bind to IL-17C; and that while Chen may describe and enable antibodies that bind to IL-17C, the reference does not explicitly describe and can not enable the skilled artisan to make antibodies that both bind to IL-17C and block binding of IL- 17C to IL-17RE. This argument is not persuasive because "a reference is not limited to the disclosure of specific working examples." *In re Mills*, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972). In the instant case, Chen teaches the polypeptide sequence of the IL-17C, and antibodies thereto, and the techniques of making antibodies to a polypeptide of known sequence have well been established in the art. Therefore, one skilled in the art would be readily able to make the antibody of the present claims following Chen's teachings *even if* Chen had not actually made the antibody. Further, as addressed above, Chen teaches that IL-17C is a stimulating PRO polypeptide (stimulates TNF- α production), and antibodies to stimulating PRO polypeptides can block the stimulating effect of the molecules produce a net inhibitory effect and can be used to suppress the T cell mediated immune response by inhibiting T cell proliferation/activation and/or lymphokine secretion, and blocking the stimulating effect of the polypeptides, and can be used to treat T cell mediated diseases such as psoriasis. Therefore, it is instantly clear that Chen teaches the use of anti-IL-17C antibody to block the stimulating effect of the molecule for the disease treatment (psoriasis, for example). Although Chen does not explicitly mention that the antibody for IL-17C would block binding of the IL-17C to the IL-17RE of SEQ ID NO:12 (as in the present claim 33), such would be the inherent property once the antibody is applied to the psoriasis patients.

At pages 7-8 of the response, the applicant further argues that it is well known in the art that antibodies that bind to a ligand do not necessarily antagonize the ligand, e.g., do not block binding of the ligand to its receptor, thus, a generic disclosure of how to make antibodies against IL-17C can not inherently anticipate antibodies that have the required property of blocking binding of IL-17C to IL-17RE; that this property would only be inherent in inhibitory antibodies to IL-17C if IL-17RE was the only receptor that mediated the signaling of IL-17C, however, the art suggests otherwise, for example, US2006/0142192 A1 (Example 33) teaches that IL-17C binds to IL-17R as well as IL-17RE; and that because of these reports that IL-17C binds to other members of the IL-17 receptor family, the skilled artisan can not be certain that IL-17C signaling is mediated only by IL-17RE, thus, the skilled artisan can not be certain that every inhibitory antibody to IL-17C would block binding of IL-17C to IL-17RE. This argument is not persuasive because, as addressed above, Chen indeed teaches the antibodies that block the stimulating effect of the molecules (including IL-17C), which would be effective for disease treatment. Further, it is irrelevant as to how many receptors IL-17C may bind because so long as blocking binding of IL-17C to IL-17RE is a part of the action (which is inherent since the active ingredient, method steps and patient population are the same in the prior art reference and the instant invention), the reference anticipates the claims. The issue is further irrelevant given the fact that the present invention uses the same antibody, i.e., the antibody that binds to IL-17C (the ligand, rather than specific receptors) and blocks its effect, thus, it would be inevitable that the antibody used in the present invention would blocking the binding of IL-17C to all potential receptors. Further, the limitation "blocks binding of the IL-17C protein to the ECD of a human IL-17RE protein" in the present claim 33 does not exclude blocking binding of the IL-17C to any other potential receptor, which is also impossible to achieve *in vivo*. Thus, applicants argue a point that is not within the limitation of the claim, therefore, is irrelevant.

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/20/07